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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,886	09/19/2003	Andrew H. Segal	11111/2003E	6806

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,886	SEGAL ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-11* is/are rejected.

7)☒ Claim(s) *1 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-11 are pending. Claim 4 is withdrawn from examination because the claim is directed to a ligand for CD40, and not a ligand for a cytokine receptor as elected. Claims 1-3 and 5-11 are under examination.

Claim Objections

2. Claims 1 and 3 are objected to because of the following informalities: In Applicant's previous response, Applicant submits that Applicant has amended the claims to exclude "vaccine". However, this is not noted for claim 3. Claim 3 still refers to the composition of claim 1 as a "vaccine composition". Additionally, the recitation "vaccine composition", claim 1, line 9, should be "composition". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo.[1]

In response to the rejection, Applicant argues that Hoo does not anticipate the claimed invention because Hoo does not teach a composition comprising fusion

[1] Hoo, W. U.S. Patent No. 5891432, published 04/06/1999.

polypeptide that is not bounded to a cell.

Applicant's arguments have been considered, however, it is not found persuasive. Contrary to Applicant's assertion, Hoo does teach a composition comprising fusion polypeptide that is both bounded and not bounded to a cell. The Office directs Applicant's attention to Example II of Hoo. At the cited example, Hoo administered unwashed cells expressing the composition. Hoo did not wash these cells to eliminate from the composition wherein the fusion polypeptide is not bounded to a cell. Thus, Hoo inherently teaches both bounded and unbounded compositions. In the instant case, it is found that the procedure used by Hoo to administer both bounded and unbounded compositions is the same as Applicant. Per Applicant's disclosure, Applicant teaches that the administration of unwashed cells expressing the bounded compositions also includes unbounded compositions. See pages 176-178 of Applicant's disclosure. It remains that Hoo teaches the claimed invention. In the instant case, it is clearly established by the Office that the claimed invention is anticipated by the cited prior art, Hoo

The claims are directed to a composition comprising a virus or cell, and a fusion polypeptide comprising i) a first amino acid sequence that comprises a cell-surface binding moiety and ii) a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein the virus or cell and the fusion polypeptide are bounded and unbounded together. Claim 2, which depends on claim 1, limits the second amino acid sequence to a ligand for a cytokine receptor, which is limited to GM-CSF by claim 3. Claim 5, which depends on claim 1, requires the cell to be a tumor cell,

a bacterial cell, a fungal cell, a cell of a parasite, a mammalian cell or an insect cell. Claim 6, which depends on claim 5, requires the cell to be a pathogenic cell. Claim 7, which depends on claim 5, requires the cell to be an attenuated cell. Claim 8, which depends on claim 1, requires the cell to be unable to divide. Claim 9, which depends on claim 1, requires the leukocyte to be an antigen presenting cell, which is specified as a professional antigen presenting cell by claim 10 and dendritic cell by claim 11.

Hoo teaches a composition. [Claims 13-24, in particular.] The composition of Hoo comprises a cell and a fusion polypeptide. [Claims 1-12, in particular.] In the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together. [Claim 1 and claim 12, in particular.] The antigen that Hoo teaches includes a virus, a bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, pathogenic and attenuated antigens, and a cell that is substantially unable to divide. [Lines 35-45, column 10, and columns 9-18, in particular.]

The first amino acid sequence in the fusion polypeptide of Hoo comprises the sequence to a membrane attachment domain, a cell-surface binding moiety. The second amino acid sequence in the fusion polypeptide of Hoo comprises the sequence of a ligand for a cell surface polypeptide of a leukocyte. Specifically, the ligand for a cell surface polypeptide of a leukocyte is a ligand for a cytokine receptor. In particular, the ligand for a cytokine receptor that Hoo teaches is GM-CSF. [Example I, column 22, in particular.] The ligand for a cell surface polypeptide used by Hoo is a ligand for a ligand for a cell surface polypeptide of a leukocyte, wherein the leukocyte is dendritic cells, which is a professional antigen presenting cell. [Columns 1-2, in particular.] In the

instant case, the composition of Hoo is the same as the claimed invention. Therefore, the claimed invention is anticipated by Hoo.

Double Patenting

5. In response to the double patenting rejections set forth in the previous office action, and restated below, Applicant submits that a terminal disclaimer will be timely filed upon notification of allowable subject matter by the Office.

Applicant's intention is noted. However, until the rejections are properly addressed, with the submission of a terminal disclaimer, all double patenting rejections are maintained for the reason(s) set forth in the record.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-29 of copending Application No. 10/224661 in view of Faulkner et al.[2]

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin and a naturally occurring GM-CSF molecule.

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g., autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The other difference between the two set of claims is that claim 1 of instant patent application is directed to a genus of fusion polypeptides, whereas, claim 1 of the conflicting patent application is directed to a species of fusion polypeptides. The fusion polypeptide of claim 1 of the conflicting patent application falls entirely within the scope of the claim 1 of the instant patent application. The lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin is the first amino acid sequence that comprises a cell-surface binding

[2] Faulkner et al. IL-2 linked to a peptide from influenza hemagglutinin enhances T cell activation by affecting the antigen-presentation function of bone marrow-derived dendritic cells. International Immunology, 2001, Vol. 13, No. 6, 713-721.

moiety, and the naturally occurring GM-CSF molecule is the second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of copending Application No. 10/666898 in view of Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a nucleic acid composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations “first amino acid sequence comprising a cell-surface binding moiety” and “carbohydrate binding domain”.

However, a carbohydrate binding domain is encompassed by the generic recitation “first amino acid sequence comprising a cell-surface binding moiety”.

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to obtain the coding sequence of the fusion to express/make the fusion polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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